

### REMARKS

Claims 1-22 and 46 are pending in the application. Claims 1-15, 17-22 and 46 are rejected. Claim 16 is objected to as being dependent on a rejected base claim.

#### Allowable Subject Matter

Applicants acknowledge the indication of allowable subject matter in claim 16 and have incorporated this subject matter together with the subject matter of claim 1 in new independent claim 47. Applicants further add new claims 48-68 dependent on new claim 47 and corresponding to pending dependent claims 2-22. These claims are fully supported by the specification and are likewise allowable as dependent on claim 47, which incorporates the allowable subject matter of claim 16.

#### Claim Rejections – 35 USC § 103

Claims 1, 3, 6-10, and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,445,630 to Richmond ("Richmond") in view of U.S. Pat. No. 3,938,502 to Scislowicz ("Scislowicz"), further in view of U.S. Pat. No. 5,766,211 to Wood ("Wood"). Claims 2 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richmond in view of Scislowicz. Applicants respectfully traverse as set forth below.

Regarding claim 1, the Office Action alleges that Richmond discloses all but the snap fit and differing materials. (pages 3-4). The Office Action cites Scislowicz and Wood respectively as disclosing these features. (*Id.*).

The Richmond figure 6 referenced in the Office Action does not, however, disclose a device within inlet and outlet ports and an injection port for injection or mixing of medical fluids. Rather, "FIG. 6 shows a spike 174 which is a vented spike, i.e., the spike 174 has a gas tube 176 defining a gas passage way 178." (Richmond, col. 6, lines 38-55). The very purpose of the illustrated "ball 184 . . . within the gas passageway 178 [is to] contact a seat 186 that is formed in the gas tube 176 to block fluid flow through the gas passageway 178 [and] gas will urge the ball 184 away from the seat 186 to permit the gas to pass out of the passageway 180."

(col. 6, lines 43-47). Similarly, Richmond's hydrophobic membrane 182 is designed to permit gas to pass out of the passageway. Given the operation and purpose of membrane 182, ball 184 and seat 186 and passageways 176 and 178, Richmond cannot be considered as disclosing an injection port as suggested by the labeled Fig. 6 of Richmond included in the Office Action. The passages cited in the Office Action, (col. 6, lines 18-53) regarding valves and membranes describe the first outlet port valve system which is not penetrated by a needle and the gas vent valve membrane which is also not penetrated by a needle.

A similar "air channel 17" and "air filter 46" are likewise disclosed in Scislowicz. (col. 6, lines 7-9, 40-45). Such structures serve to equalize pressures and vent gases to prevent generation of vacuums during fluid transfer that would otherwise inhibit fluid transfer and simply are not injection ports. Thus, one of skill in the art would not consider nor seek to use air passageway 61 containing an air filter 63 as an injection port.

Also, the hydrophobic membrane 182 of Richmond is arranged to let gas (*i.e.* a fluid) pass therethrough (*see* col. 6, lines 43-53).

Accordingly, neither Richmond nor Scislowicz disclose "an *injection port* for injection of a second medical fluid . . . being sealed by a **fluid-proof membrane** which can be penetrated by an injection needle," as recited in claims 1 and 46. (emphasis added).

Moreover, Richmond does not allow for mixing of fluids via several ducts and ports, but for gas venting from a single fluid. Thus, Richmond also fails to disclose "an outlet port for exit of a *mixed flow* of said first and second medical fluids, a *first duct extending between said injection port and said inlet port*, and a second duct extending between said inlet port and said outlet port, said injection port being sealed by a fluid-proof membrane which can be penetrated by an injection needle when injecting said second medical fluid," as recited in claims 1 and 46. (emphasis added).

Richmond further fails to disclose a device comprising "at least a first portion made of a first material and a second portion made of a second material, wherein said *second material is substantially more resilient* than said first material, and said inlet port and said injection port are included in said first portion and said outlet port is included in said second portion wherein said

first and second portions are mutually configured to facilitate attachment to each other by means of a *combined friction coupling and snap connection* providing a first retention force,” as recited in claims 1 and 46. (emphasis added).

The Office Action recognizes that “Richmond is silent with regard to the materials used to construct the second part of the connector,” and instead cites Wood as disclosing use of rigid and elastic materials. (page 4). Applicants maintain that Richmond does not disclose a device comprising “a first portion made out of a first material and a second portion made of a second material, wherein the second material is substantially more resilient than the first material,” as recited in claims 1 and 46. Figure 6 of Richmond merely shows a device with different cross-section markings to differentiate components.

Figures 5 and 6 of Richmond show devices comprising a reciprocally disposed valve element 166 (see figures 5 and 6 and col. 6, lines 18-23). The bottom part of the Richmond device must be rigid to allow the valve element 166 to move reciprocally therein. If the bottom part of the Richmond device was made out of resilient material, this could adversely affect the movement and sealing effectiveness of Richmond’s valve element 166. Thus, one of skill in the art would not consider making the outlet or bottom portion of the Richmond device out of a material that is substantially more resilient than the inlet or top portion of the Richmond device.

Wood discloses a device comprising elastic cylinders (25, 5, 6) pulled over the ends of a y-connector housing (12), i.e., the part to which a syringe 14 is connected is made out of more resilient material in Wood’s device. This is the very opposite of claim 1, which recites a device in which the “second material is substantially more resilient than said first material, and . . . said outlet port is included in said second portion,” i.e., the outlet port is the more resilient portion.

Richmond does not disclose a device comprising two “portions [that] are mutually configured to facilitate attachment to each other by means of a combined friction coupling and snap connection,” as recited in claim 1. The Office Action cites Scislowicz as disclosing these limitations and asserts that it would be obvious to modify the device disclosed by Richmond by connecting the differently cross-hatched portions of Richmond’s device using Scislowicz’s snap fit.

Scislowicz discloses a particular snap fit connection between the ridge 76 of the transfer unit 55 and the undercut 75 of the closure portion 57, as shown in Figure 9. Scislowicz's snap fit includes a resilient transfer unit portion and a rigid closure portion. Because the rigid container neck would restrict outward deformation of closure 57 during connection with transfer unit 55, one of ordinary skill in the art would not seek to make the closure portion, allegedly corresponding to the claimed second portion, out of a resilient material as claimed.

The cooperation of the resilient portion and the rigid portion in the snap fit connection is part of the claimed device of claims 1 and 46 comprising a "*second portion made of a second material. . . wherein said second material is substantially more resilient* than said first material, and said inlet port and said injection port are included in said first portion and *said outlet port is included in said second portion* wherein said first and second portions are mutually configured to facilitate attachment to each other by means of a *combined friction coupling and snap connection* providing a first retention force." None of the cited references or cited combination of references disclose the claimed combination of material properties and connection types.

Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Redmond in view of Scislowicz, in view of Wood, and further in view of U.S. Pat. No. 6,142,446 to Leinsing ("Leinsing"). Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Redmond in view of Scislowicz, in view of Wood, and further in view of U.S. Pat. No. 6,146,362 to Turnbull et al. ("Turnbull"). Applicants traverse these rejections for similar reasons as set forth with regard to claims 1 and 46.

Accordingly, Applicants submit that the cited combination of Richmond, Scislowicz, Wood, Leinsing and Turnbull do not disclose each of the limitation of claims 1 or 46. Claims 2, 3, 6-10, 11-14-22 are likewise allowable as depending from claim 1. Thus, Applicants request withdrawal of the rejections under Section 103.

#### CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or

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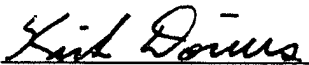
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concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reason for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to amendment. Applicants respectfully request consideration of all filed IDS' not previously considered, by initialing and returning each Form 1449.

Applicant requests a three-month extension of time. All fees are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply all charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 19497-011001.

Respectfully submitted,

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